

**REMARKS**

**I. STATUS OF THE CLAIMS**

Claims 11-28, and 31-32 are cancelled without prejudice to future prosecution. Claims 1 and 9 have been amended to specify that the claimed cancer treatment methods employ the recited compounds as the active agent in treating cancer, rather than a compound for treating the symptoms of cancer. Support for the amendment may be found, for example, in Applicants' specification at page 7, lines 14-17, stating: "The present invention relates to methods of preventing or treating cancer using low molecular weight antioxidants ... *as the active agent* or as a chemo-and/or radio-protectant (emphasis added)." Therefore no new matter is entered with this amendment.

With entry of this amendment, claims, 1, 5, 7, 8, 9, and 29-30 are pending.

**II. REJECTION UNDER 35 USC §103**

Claims 1, 5, 7, 9, and 29-30 stand rejected as allegedly obvious over Fridovich (WO 99/23097) in view of Kobayashi, and over Kobayashi in view of Bloodsworth et al. The Examiner asserts that Fridovich teaches the use of pyridyl-substituted porphyrins as superoxide dismutase mimetics; Bloodsworth teaches the use of compound 10113 as a superoxide dismutase mimetic; and Kobayashi teaches "to employ superoxide dismutase mimetic for treating cancer patient to relieve oxidative stress." See Official Action dated Feb. 16, 2006 at page 7. From these asserted teachings, the Examiner concludes that it would have been obvious for one skilled in the art to employ compound 10113 as a superoxide dismutase (SOD) mimetic to treat cancer. Applicants respectfully disagree.

**A. The claims as amended do not encompass methods of treating cancer symptoms**

As a preliminary matter, Applicants note that claims 1 and 9 have been amended to specify that the claimed cancer treatment methods employ the recited compound as the *active agent* in treating cancer, rather than a compound for treating the symptoms of cancer. Applicants' specification explicitly distinguishes between active agents and compounds for treating cancer symptoms at page 7, lines 14-17 (stating "The present invention relates to

methods of preventing or treating cancer using low molecular weight antioxidants ... ***as the active agent*** or as a chemo-and/or radio-protectant (emphasis added)."

Therefore, Kobayashi's teachings regarding the use of PS-K in treating the symptoms of cancer are irrelevant to the currently pending claims. Applicants submit that the only statement in Kobayashi even arguably relevant to the claims as amended occurs at page 58, stating "PS-K may serve to inhibit the progress of malignancy by reducing OS."

Moreover, the Examiner is respectfully reminded that limitations in the preamble of a claim must be given patentable weight where the claim preamble is "'necessary to give life, meaning and vitality' to the claim." See MPEP § 2111.02, citing *Pitney Bowles, Inc. v. Hewlett-Packard Co.*, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999); See also *Jansen v. Rexall Sundown, Inc.*, 68 USPQ2d 1154, 1158 (Fed. Cit. 2003), (In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient "in need" gives life and meaning to the preamble's statement of purpose).

#### **B. The combination of references fail to provide a reasonable expectation of success**

In order to establish a proper prima facie case of obviousness, ***there must be a reasonable expectation of success***. See MPEP § 2143; *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants respectfully submit that a proper prima facie case of obviousness has not been set forth because none of the references, either alone or in combination, would provide one skilled in the art with a reasonable expectation of successfully using the claimed porphyrin compound as an active agent to treat cancer.

First, Kobayashi's teachings are limited to ***only one*** SOD mimetic: The protein bound polysaccharide PS-K. This polysaccharide shares no structural similarities to Applicants' claimed porphyrin anti-cancer compound. Without guidance to the contrary, one skilled in the art would immediately recognize that teachings limited to a single SOD mimetic would not necessarily apply to all SOD mimetics known in the art, particularly where no structural similarities are present. In fact, the Examiner asserts that the "art for treating cancers are unpredictable" and that the "pharmaceutical art is unpredictable, requiring each embodiment to

be individually assessed of physiological activity.” See Official Action at pages 5 and 6. Given the Examiner’s assertion that the cancer treating and pharmaceutical arts are unpredictable, one skilled in the art could not reasonably expect to successfully treat cancer with structurally unrelated SOD mimetics (e.g. porphyrins) based on Kobayashi’s limited reference to a single structurally unrelated SOD mimetic (i.e. PS-K).

Second, Kobayashi did not instruct those skilled in the art to use a superoxide dismutase mimetic as an active agent in the treatment of cancer. Rather, Kobayashi merely invited those skilled in the art to consider the possibility of using PS-K, and PS-K only, as an anti-cancer agent: “PS-K *may serve* to inhibit the progress of malignancy by reducing OS.” See Kobayashi at page 58 (emphasis added). An invitation to try PS-K as an anti-cancer agent, however, does not establish a reasonable expectation of successfully using PS-K as an anti-cancer agent. In fact, the Federal Circuit has unequivocally stated: "'Obvious to try' has long been held not to constitute obviousness." *In re Deuel*, 51 F.3d 1552, 1559 (Fed.Cir. 1995).

Third, neither Kobayashi nor any other cited reference provides a single piece of data indicating that PS-K is a viable active agent in the treatment of cancer. Thus, after examining the cited references, one skilled in the art would be unsure whether PS-K itself could be used as an anti-cancer compound, much less structurally unrelated compounds such as compound 10113. Kobayashi’s vague speculation regarding a single SOD mimetic, PS-K, should not foreclose patentability of the entire class of SOD mimetics as active agents in the treatment of cancer.

Moreover, Applicants have disclosed to the world, for the first time, data proving the utility of porphyrin SOD mimetics as active agents in the treatment of cancer. After disclosing this valuable information, it would be unfair to deny Applicants a commercial advantage based on a purely speculative statement in a single publication, without any anti-cancer studies, and without any anti-cancer data.

No sound technical or logical reasoning has been set forth as to why the skilled artisan would reasonably expect to successfully use PS-K as an anti-cancer compound given the fact that none of the references provide any anti-cancer studies, or any anti-cancer data for PS-K. Even assuming *arguendo* that one skilled in the art would reasonably expect to successfully use PS-K as an active agent to treat cancer, none of the references have provided any reasons to expect structurally unrelated SOD mimetics, such as compound 10113, to function in exactly the same

manner. The lack of a reasonable expectation of success is especially glaring given the Examiner's assertion that the cancer treating and pharmaceutical arts are unpredictable.

Because a reasonable expectation of successfully using Applicants' claimed porphyrins as an active agent in the treatment of cancer has not been established with respect to the pending claims, withdrawal of the obviousness rejection is respectfully requested.

### **III. DOUBLE PATENTING REJECTIONS**

Claims 1, 5, 7, 9, 29, and 29-30 stand provisionally under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-32 of U.S. Patent No. 6,916,799 in view of Kobayashi.

As discussed above, one skilled in the art would not reasonably expect to successfully use PS-K as an active agent in the treatment of cancer given the fact that neither Kobayashi nor the '799 patent provides any anti-cancer studies, or any anti-cancer data for PS-K. Moreover, neither reference provides a reason to expect structurally unrelated SOD mimetics, such as compound 10113, to function in exactly the same way as PS-K. Given the Examiner's assertion that the cancer treating and pharmaceutical arts are unpredictable, Applicants' claimed invention cannot be considered obvious. Therefore, withdrawal of the double patenting rejection is respectfully requested.

### **IV. REJECTION UNDER 35 U.S.C. § 112 - ENABLEMENT**

The Examiner states that claims 1, 4, 7, 8, 9, and 29-30 are enabling for treating cancer patients by modulating levels of oxidants. Applicants have amended claims 1 and 9 to specify that the "mimetic of an enzymatic scavenger of reactive oxygen species" is "*an active agent*" in the treatment of the cancer (emphasis added). Therefore, after reading the claims as amended, one skilled in the art would immediately understand that the claimed treatment of cancer is dependent upon the activity of the mimetic as an enzymatic scavenger of reactive oxygen species. Because enzymatic scavengers modulate levels of oxidants, Applicants submit that the claims as amended are fully enabled. Therefore, in light of the amendment to claims 1 and 9, Applicants respectfully request withdrawal of the enablement rejection.

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### CONCLUSION

In view of the above amendments and remarks, it is believed that the application is in condition for allowance, and such action is respectfully requested at the Examiner's earliest convenience.

Applicants hereby authorize the Commissioner to charge any fee due herein and any other fees that may become due or credit become payable to Deposit Account No. 50-2613 during the pendency of this application.

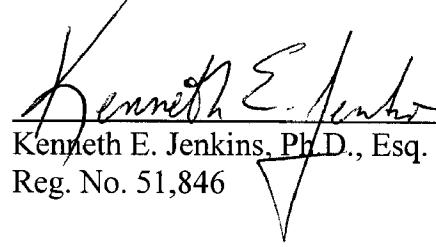
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The Examiner is invited to telephone the undersigned to facilitate advancement of the present application.

Respectfully Submitted,

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